

***Electromagnetic Emissions Test Report
In Accordance With
FCC Part 15 Section 15.231
on the
Therasense (Abbott Diabetes Care)
Transmitter
Model: Navigator Continuous Glucose Monitor***

FCC ID: QXSTX111004


GRANTEE: Therasense (Abbott Diabetes Care)
1360 South Loop Road
Alameda, CA 94502

TEST SITE: Elliott Laboratories, Inc.
684 W. Maude Ave
Sunnyvale, CA 94086

REPORT DATE: October 21, 2004

FINAL TEST DATE: October 8, 2004

AUTHORIZED SIGNATORY:



Mark Briggs
Vice President of Engineering



Elliott Laboratories, Inc. is accredited by the A2LA, certificate number 2016-01, to perform the test(s) listed in this report. This report shall not be reproduced, except in its entirety, without the written approval of Elliott Laboratories, Inc.

TABLE OF CONTENTS

COVER PAGE	1
TABLE OF CONTENTS	2
SCOPE	3
OBJECTIVE	3
STATEMENT OF COMPLIANCE	4
TEST RESULTS SUMMARY	4
15.231 / RSS 210 SECTION 6.1	4
MEASUREMENT UNCERTAINTIES	5
EQUIPMENT UNDER TEST (EUT) DETAILS	6
GENERAL.....	6
ENCLOSURE	6
MODIFICATIONS.....	6
SUPPORT EQUIPMENT.....	6
EUT INTERFACE PORTS	6
EUT OPERATION	7
ANTENNA SYSTEM	7
TEST SITE	8
GENERAL INFORMATION.....	8
CONDUCTED EMISSIONS CONSIDERATIONS.....	8
RADIATED EMISSIONS CONSIDERATIONS	8
MEASUREMENT INSTRUMENTATION	9
RECEIVER SYSTEM.....	9
INSTRUMENT CONTROL COMPUTER.....	9
LINE IMPEDANCE STABILIZATION NETWORK (LISN).....	9
FILTERS/ATTENUATORS.....	10
ANTENNAS.....	10
ANTENNA MAST AND EQUIPMENT TURNTABLE.....	10
INSTRUMENT CALIBRATION.....	10
TEST PROCEDURES	11
EUT AND CABLE PLACEMENT	11
CONDUCTED EMISSIONS.....	11
RADIATED EMISSIONS	11
SPECIFICATION LIMITS AND SAMPLE CALCULATIONS	12
CONDUCTED EMISSIONS SPECIFICATION LIMITS, SECTION 15.207 & 15.107(A).....	12
FUNDAMENTAL AND HARMONIC LIMITS 15.231 (B) / RSS 210 TABLE 1	12
FUNDAMENTAL AND HARMONIC LIMITS 15.231 (E)/RSS 210 TABLE 4.....	13
SAMPLE CALCULATIONS - CONDUCTED EMISSIONS.....	13
SAMPLE CALCULATIONS - RADIATED EMISSIONS	14
EXHIBIT 1: Test Equipment Calibration Data	1
EXHIBIT 2: Test Measurement Data	2
EXHIBIT 3: Photographs of Test Configurations.....	3
EXHIBIT 4: Detailed Photographs of.....	4
EXHIBIT 5: Block Diagram of.....	5
EXHIBIT 6: Schematic Diagrams of.....	6
EXHIBIT 7: Theory of Operation for	7
EXHIBIT 8: Operator's Manual	8

SCOPE

An electromagnetic emissions test has been performed on the Therasense (Abbott Diabetes Care) model Navigator Continuous Glucose Monitor pursuant to Subpart C of Part 15 of FCC Rules for intentional radiators. Conducted and radiated emissions data has been collected, reduced, and analyzed within this report in accordance with measurement guidelines set forth in ANSI C63.4-2003 as outlined in Elliott Laboratories test procedures.

The intentional radiator above has been tested in a simulated typical installation to demonstrate compliance with the relevant Industry Canada performance and procedural standards.

Final system data was gathered in a mode that tended to maximize emissions by varying orientation of EUT, orientation of power and I/O cabling, antenna search height, and antenna polarization.

Every practical effort was made to perform an impartial test using appropriate test equipment of known calibration. All pertinent factors have been applied to reach the determination of compliance.

The test results recorded herein are based on a single type test of the Therasense (Abbott Diabetes Care) model Navigator Continuous Glucose Monitor and therefore apply only to the tested sample. The sample was selected and prepared by Chris Cherrison of Therasense (Abbott Diabetes Care).

OBJECTIVE

The primary objective of the manufacturer is compliance with Subpart C of Part 15 of FCC Rules for the radiated and conducted emissions of intentional radiators. Certification of these devices is required as a prerequisite to marketing as defined in Part 2 the FCC Rules.

Certification is a procedure where the manufacturer or a contracted laboratory makes measurements and submits the test data and technical information to the FCC. The FCC issues a grant of equipment authorization upon successful completion of their review of the submitted documents. Once the equipment authorization has been obtained, the label indicating compliance must be attached to all identical units, which are subsequently manufactured.

Maintenance of compliance is the responsibility of the manufacturer. Any modification of the product which may result in increased emissions should be checked to ensure compliance has been maintained (i.e., printed circuit board layout changes, different line filter, different power supply, harnessing or I/O cable changes, etc.).

STATEMENT OF COMPLIANCE

The tested sample of Therasense (Abbott Diabetes Care) model Navigator Continuous Glucose Monitor complied with the requirements of Subpart C of Part 15 of the FCC Rules for low power intentional radiators.

Maintenance of FCC compliance is the responsibility of the manufacturer. Any modification of the product which may result in increased emissions should be checked to ensure compliance has been maintained (i.e., printed circuit board layout changes, different line filter, different power supply, harnessing or I/O cable changes, etc.).

TEST RESULTS SUMMARY**15.231 / RSS 210 Section 6.1**

FCC Part 15 Section	Description	Comments	Result
15.207 / 15.107	AC Conducted Emissions, 0.15 – 30 MHz	Not applicable – the device is not intended to be powered, directly or indirectly, from an AC power source	N/A
15.231 (a) (1)	Duration of manually activated transmission	Not applicable – device transmits at periodic intervals and operates under 15.231(e)	N/A
15.231 (a) (2)	Duration of automatically activated transmission		
15.231 (a) (3)	Transmissions at predetermined / regular intervals are not permitted		
15.231 (a) (4)	Pendency of transmissions used during emergencies involving fire, security, and safety of life		
15.231 (c)	Bandwidth	Maximum permitted is 0.25% of the operating frequency (1.084 MHz). Measured bandwidth was 253 kHz	Pass
15.231 (d)	Frequency Stability	Only applicable to devices in the 40.66 – 40.70 MHz band	N/A
15.231 (e)	Transmitter Radiated Emissions, 433.6 MHz	67.9dB μ V/m (2483.1 μ V/m) @ 433.564MHz (-5.0dB)	Pass
15.231 (e)	Transmitter Radiated Spurious Emissions, 30-4336 MHz	37.3dB μ V/m (73.3 μ V/m) @ 867.128MHz (-15.6dB)	Pass
15.231 (e)	Duration of automatically activated transmission	20ms transmit time at an interval of 60 seconds during normal operation. 15.231(e) requires a duration of less than 1 second at an interval of more than 30 times the duration of the transmissions and at least 10 seconds	Pass

Note 1 – Refer to the operational description included with this application for detailed description and timing diagrams for transmission duration.

Note 2 – As the device is intended for hand-held operation it was tested in all three orthogonal orientations.

MEASUREMENT UNCERTAINTIES

ISO Guide 17025 requires that an estimate of the measurement uncertainties associated with the emissions test results be included in the report. The measurement uncertainties given below are based on a 95% confidence level and were calculated in accordance with NAMAS document NIS 81.

Measurement Type	Frequency Range (MHz)	Calculated Uncertainty (dB)
Conducted Emissions	0.15 to 30	± 2.4
Radiated Emissions	30 to 1000	± 3.6

EQUIPMENT UNDER TEST (EUT) DETAILS**GENERAL**

The Therasense (Abbott Diabetes Care) model Navigator Continuous Glucose Monitor is a portable battery-operated device that continuously monitors and records subcutaneous glucose levels. It has an additional function of issuing hypoglycemic and hyperglycemic alarms based on user set levels. The system is comprised of two modules, a transmitter and receiver. The transmitter mounts directly on the skin, and the receiver is placed on a tabletop or worn/carried like a pager during operation. The EUT was, therefore, treated as tabletop equipment during testing to simulate the end-user environment. The electrical rating of the EUT is 3V (battery operated).

The sample was received and tested on October 8, 2004.

The EUT consisted of the following component(s):

Manufacturer	Model	Description	Serial Number	FCC ID
Therasense (Abbott Diabetes Care)	Navigator Transmitter	Glucose-Level Monitor Transmitter	AAAF188-80293	QXSTX111004

ENCLOSURE

The Navigator Transmitter enclosure is primarily constructed of plastic. It measures approximately 5.3 cm wide by 3.0 cm deep by 1.2 cm high.

MODIFICATIONS

The EUT did not require modifications during testing in order to comply with emissions specifications.

SUPPORT EQUIPMENT

The following equipment was used as local support equipment for emissions testing:

Manufacturer	Model	Description	Serial Number	FCC ID
Therasense (Abbott Diabetes Care)	PRT03981	Sim-Vivo	-	-

No remote support equipment was used during emissions testing.

EUT INTERFACE PORTS

No I/O cabling configuration was used during emissions testing.

EUT OPERATION

The transmitter was configured normally to transmit data to the receiver once per 20 seconds. The Sim-Vivo was connected to the transmitter to simulate the data that would be obtained from a sensor that would normally be used. The sensor cannot be used since it only provides data when embedded in the skin of a user.

ANTENNA SYSTEM

The antenna system used with the Therasense (Abbott Diabetes Care) model Navigator Continuous Glucose Monitor transmitter is integral to the PC board.

TEST SITE

GENERAL INFORMATION

Final test measurements were taken on October 8, 2004 at the Elliott Laboratories Open Area Test Site #2 located at 684 West Maude Avenue, Sunnyvale, California. Pursuant to section 2.948 of the FCC's Rules and section 3.3 of RSP-100, construction, calibration, and equipment data has been filed with the Commission.

ANSI C63.4 recommends that ambient noise at the test site be at least 6 dB below the allowable limits. Ambient levels are below this requirement with the exception of predictable local TV, radio, and mobile communications traffic. The test site contains separate areas for radiated and conducted emissions testing. Considerable engineering effort has been expended to ensure that the facilities conform to all pertinent requirements of ANSI C63.4-1992.

CONDUCTED EMISSIONS CONSIDERATIONS

Conducted emissions testing is performed in conformance with ANSI C63.4-2003. Measurements are made with the EUT connected to the public power network through a nominal, standardized RF impedance, which is provided by a line impedance stabilization network, known as a LISN. A LISN is inserted in series with each current-carrying conductor in the EUT power cord.

RADIATED EMISSIONS CONSIDERATIONS

The FCC has determined that radiation measurements made in a shielded enclosure are not suitable for determining levels of radiated emissions. Radiated measurements are performed in an open field environment. The test site is maintained free of conductive objects within the CISPR defined elliptical area incorporated in ANSI C63.4 guidelines.

MEASUREMENT INSTRUMENTATION**RECEIVER SYSTEM**

An EMI receiver as specified in CISPR 16-1 is used for emissions measurements. The receivers used can measure over the frequency range of 9 kHz up to 2000 MHz. These receivers allow both ease of measurement and high accuracy to be achieved. The receivers have Peak, Average, and CISPR (Quasi-peak) detectors built into their design so no external adapters are necessary. The receiver automatically sets the required bandwidth for the CISPR detector used during measurements.

For measurements above the frequency range of the receivers, a spectrum analyzer is utilized because it provides visibility of the entire spectrum along with the precision and versatility required to support engineering analysis. Average measurements above 1000MHz are performed on the spectrum analyzer using the linear-average method with a resolution bandwidth of 1 MHz and a video bandwidth of 10 Hz.

INSTRUMENT CONTROL COMPUTER

The receivers utilize either a Rohde & Schwarz EZM Spectrum Monitor/Controller or contain an internal Spectrum Monitor/Controller to view and convert the receiver measurements to the field strength at an antenna or voltage developed at the LISN measurement port, which is then compared directly with the appropriate specification limit. This provides faster, more accurate readings by performing the conversions described under Sample Calculations within the Test Procedures section of this report. Results are printed in a graphic and/or tabular format, as appropriate. A personal computer is used to record all measurements made with the receivers.

The Spectrum Monitor provides a visual display of the signal being measured. In addition, the controller or a personal computer run automated data collection programs which control the receivers. This provides added accuracy since all site correction factors, such as cable loss and antenna factors are added automatically.

LINE IMPEDANCE STABILIZATION NETWORK (LISN)

Line conducted measurements utilize a fifty microhenry Line Impedance Stabilization Network as the monitoring point. The LISN used also contains a 250 uH CISPR adapter. This network provides for calibrated radio frequency noise measurements by the design of the internal low pass and high pass filters on the EUT and measurement ports, respectively.

FILTERS/ATTENUATORS

External filters and precision attenuators are often connected between the receiving antenna or LISN and the receiver. This eliminates saturation effects and non-linear operation due to high amplitude transient events.

ANTENNAS

A biconical antenna is used to cover the range from 30 MHz to 300 MHz and a log periodic antenna is utilized from 300 MHz to 1000 MHz. Narrowband tuned dipole antennas are used over the entire 30 to 1000 MHz range for precision measurements of field strength. Above 1000 MHz, a horn antenna is used. The antenna calibration factors are included in site factors programmed into the test receivers.

ANTENNA MAST AND EQUIPMENT TURNTABLE

The antennas used to measure the radiated electric field strength are mounted on a non-conductive antenna mast equipped with a motor-drive to vary the antenna height.

ANSI C63.4 specifies that the test height above ground for table mounted devices shall be 80 centimeters. Floor mounted equipment shall be placed on the ground plane if the device is normally used on a conductive floor or separated from the ground plane by insulating material from 3 to 12 mm if the device is normally used on a non-conductive floor. During radiated measurements, the EUT is positioned on a motorized turntable in conformance with this requirement.

INSTRUMENT CALIBRATION

All test equipment is regularly checked to ensure that performance is maintained in accordance with the manufacturer's specifications. All antennas are calibrated at regular intervals with respect to tuned half-wave dipoles. An exhibit of this report contains the list of test equipment used and calibration information.

TEST PROCEDURES**EUT AND CABLE PLACEMENT**

The FCC requires that interconnecting cables be connected to the available ports of the unit and that the placement of the unit and the attached cables simulate the worst case orientation that can be expected from a typical installation, so far as practicable. To this end, the position of the unit and associated cabling is varied within the guidelines of ANSI C63.4, and the worst-case orientation is used for final measurements.

CONDUCTED EMISSIONS

Conducted emissions are measured at the plug end of the power cord supplied with the EUT. Excess power cord length is wrapped in a bundle between 30 and 40 centimeters in length near the center of the cord. Preliminary measurements are made to determine the highest amplitude emission relative to the specification limit for all the modes of operation. Placement of system components and varying of cable positions are performed in each mode. A final peak mode scan is then performed in the position and mode for which the highest emission was noted on all current carrying conductors of the power cord.

RADIATED EMISSIONS

Radiated emissions measurements are performed in two phases as well. A preliminary scan of emissions is conducted in which all significant EUT frequencies are identified with the system in a nominal configuration. At least two scans are performed from 30 MHz up to the frequency required by the regulation specified on page 1. One or more of these is with the antenna polarized vertically while the one or more of these is with the antenna polarized horizontally. During the preliminary scans, the EUT is rotated through 360°, the antenna height is varied and cable positions are varied to determine the highest emission relative to the limit.

A speaker is provided in the receiver to aid in discriminating between EUT and ambient emissions. Other methods used during the preliminary scan for EUT emissions involve scanning with near field magnetic loops, monitoring I/O cables with RF current clamps, and cycling power to the EUT.

Final maximization is a phase in which the highest amplitude emissions identified in the spectral search are viewed while the EUT azimuth angle is varied from 0 to 360 degrees relative to the receiving antenna. The azimuth, which results in the highest emission is then maintained while varying the antenna height from one to four meters. The result is the identification of the highest amplitude for each of the highest peaks. Each recorded level is corrected in the receiver using appropriate factors for cables, connectors, antennas, and preamplifier gain. Emissions, which have values close to the specification limit may also be measured with a tuned dipole antenna to determine compliance.

SPECIFICATION LIMITS AND SAMPLE CALCULATIONS

The limits for conducted emissions are given in units of microvolts, and the limits for radiated emissions are given in units of microvolts per meter at a specified test distance. Data is measured in the logarithmic form of decibels relative to one microvolt, or dB microvolts (dBuV). For radiated emissions, the measured data is converted to the field strength at the antenna in dB microvolts per meter (dBuV/m). The results are then converted to the linear forms of uV and uV/m for comparison to published specifications.

For reference, converting the specification limits from linear to decibel form is accomplished by taking the base ten logarithm, then multiplying by 20. These limits in both linear and logarithmic form are as follows:

CONDUCTED EMISSIONS SPECIFICATION LIMITS, SECTION 15.207 & 15.107(a)

The table below shows the limits for the emissions on the AC power line from an intentional radiator and a receiver.

Frequency (MHz)	Average Limit (dBuV)	Quasi Peak Limit (dBuV)
0.150 to 0.500	Linear decrease on logarithmic frequency axis between 56.0 and 46.0	Linear decrease on logarithmic frequency axis between 66.0 and 56.0
0.500 to 5.000	46.0	56.0
5.000 to 30.000	50.0	60.0

FUNDAMENTAL AND HARMONIC LIMITS 15.231 (b) / RSS 210 Table 1

The table below shows the limits for both the Fundamental and Harmonic emissions for each frequency band of operation detailed in Section 15.231 (b) for control signals.

Operating Frequency (MHz)	Field strength (microvolts/m)	Harmonics (microvolts/m)
70 - 130	1250	125
130 - 174	1250 - 3750	125 - 375
174 - 260	3750	375
260 - 470	3750 - 12,500	375 - 1250
Above 470	12,500	1250

FUNDAMENTAL AND HARMONIC LIMITS 15.231 (e)/RSS 210 Table 4

The table below shows the limits for both the Fundamental and Harmonic emissions (that do not fall in restricted bands) for each frequency band of operation detailed in Section 15.231 (e) for data signals.

Operating Frequency (MHz)	Field strength (microvolts/m)	Harmonics (microvolts/m)
70 - 130	500	50
130 - 174	500 - 1500	50 - 150
174 - 260	1500	150
260 - 470	1500 - 5000	150 - 500
Above 470	5000	500

SAMPLE CALCULATIONS - CONDUCTED EMISSIONS

Receiver readings are compared directly to the conducted emissions specification limit (decibel form) as follows:

$$R_r - S = M$$

where:

R_r = Receiver Reading in dBuV

S = Specification Limit in dBuV

M = Margin to Specification in +/- dB

SAMPLE CALCULATIONS - RADIATED EMISSIONS

Receiver readings are compared directly to the specification limit (decibel form). The receiver internally corrects for cable loss, preamplifier gain, and antenna factor. The calculations are in the reverse direction of the actual signal flow, thus cable loss is added and the amplifier gain is subtracted. The Antenna Factor converts the voltage at the antenna coaxial connector to the field strength at the antenna elements.

A distance factor, when used for electric field measurements above 30MHz, is calculated by using the following formula:

$$F_d = 20 * \text{LOG}_{10} (D_m/D_s)$$

where:

$$F_d = \text{Distance Factor in dB}$$

$$D_m = \text{Measurement Distance in meters}$$

$$D_s = \text{Specification Distance in meters}$$

For electric field measurements below 30MHz the extrapolation factor is either determined by making measurements at multiple distances or a theoretical value is calculated using the formula:

$$F_d = 40 * \text{LOG}_{10} (D_m/D_s)$$

Measurement Distance is the distance at which the measurements were taken and Specification Distance is the distance at which the specification limits are based. The antenna factor converts the voltage at the antenna coaxial connector to the field strength at the antenna elements.

The margin of a given emission peak relative to the limit is calculated as follows:

$$R_C = R_R + F_d$$

and

$$M = R_C - L_S$$

where:

R_R = Receiver Reading in dBuV/m

F_d = Distance Factor in dB

R_C = Corrected Reading in dBuV/m

L_S = Specification Limit in dBuV/m

M = Margin in dB Relative to Spec

EXHIBIT 1: Test Equipment Calibration Data

1 Page

Radiated Emissions Prescan in Chamber 2, 30 - 1,000 MHz, 08-Sep-04**Engineer: David**

<u>Manufacturer</u>	<u>Description</u>	<u>Model #</u>	<u>Asset #</u>	<u>Cal Due</u>
Elliott Laboratories	Biconical Antenna, 30-300 MHz	DM-105-T1	382	09-Sep-04
Electro Metrics	Conical log spiral antenna	LCA-25	1291	04-May-05
Hewlett Packard	RF Preamplifier, 100 kHz - 1.3 GHz	8447E	1606	28-Jul-05
Hewlett Packard	EMC Spectrum Analyzer, 9KHz - 22GHz	8593EM	1319	20-Nov-04

Radiated Emissions on OATS #1, 30 - 1,000 MHz, 08-Sep-04**Engineer: David**

<u>Manufacturer</u>	<u>Description</u>	<u>Model #</u>	<u>Asset #</u>	<u>Cal Due</u>
EMCO	Biconical Antenna, 30-300 MHz	3110B	801	09-Jul-05
Rohde & Schwarz	Test Receiver, 9kHz-2750MHz	ESCS 30	1337	05-Jan-05
EMCO	Log Periodic Antenna, 0.2-2 GHz	3148	1347	28-Oct-04

Radiated Emissions, 30 - 4,336 MHz, 08-Oct-04**Engineer: dbare**

<u>Manufacturer</u>	<u>Description</u>	<u>Model #</u>	<u>Asset #</u>	<u>Cal Due</u>
Elliott Laboratories	Tunable Dipole Antenna	(White) (410-1000 MHz)	323	16-Mar-05
EMCO	Horn Antenna, D. Ridge 1-18GHz	3115	487	13-May-06
Hewlett Packard	Microwave Preamplifier, 1-26.5GHz	8449B	870	12-Jan-05
Hewlett Packard	EMC Spectrum Analyzer 30Hz - 40 GHz, Sunnyvale	8564E (84125C)	1148	09-Jun-05
Rohde & Schwarz	Test Receiver, 0.009-2750 MHz	ESN	1332	12-May-05
EMCO	Log Periodic Antenna, 0.2-2 GHz	3148	1404	17-Nov-04
EMCO	Biconical Antenna, 30-300 MHz	3110B	1498	15-Jan-05

EXHIBIT 2: Test Measurement Data

T57081 6 Pages



EMC Test Data

Client:	Abbott Diabetes Care	Job Number:	J56294
Model:	Navigator Transmitter (SN AAAF188-80293)	T-Log Number:	T57080
Contact:	Chris Cherrison	Account Manager:	Susan Pelzl
Emissions Spec:	EN 300 220-3, FCC 15.231(e), EN 60601-1-2	Class:	B
Immunity Spec:	EN 301 489-3	Environment:	Medical

EMC Test Data

For The

Abbott Diabetes Care

Model

Navigator Transmitter (SN AAAF188-80293)

Date of Last Test: 10/8/2004



EMC Test Data

Client:	Abbott Diabetes Care	Job Number:	J56294
Model:	Navigator Transmitter (SN AAAF188-80293)	T-Log Number:	T57080
Contact:	Chris Cherrison	Account Manager:	Susan Pelzl
Emissions Spec:	EN 300 220-3, FCC 15.231(e), EN	Class:	B
Immunity Spec:	EN 301 489-3	Environment:	Medical

EUT INFORMATION

General Description

The Navigator system is a portable battery-operated device that continuously monitors and records subcutaneous glucose levels. It has an additional function of issuing hypoglycemic and hyperglycemic alarms based on user set levels. The system is comprised of two modules, a transmitter and receiver. The transmitter mounts directly on the skin, and the receiver is placed on a tabletop or worn/carried like a pager during operation. The EUT was, therefore, treated as tabletop equipment during testing to simulate the end-user environment. The electrical rating of the EUT is 3V (battery operated).

Equipment Under Test

Manufacturer	Model	Description	Serial Number	FCC ID
Abbott Diabetes Care	Navigator Transmitter	Glucose-Level Monitor Transmitter	AAAF188-80003	TBD
Abbott Diabetes Care	Navigator Transmitter	Glucose-Level Monitor Transmitter	AAAF188-80293	QXSTX111004

Other EUT Details

Sample Serial Number AAAF188-80003 was used for testing on September 8, 2004 all other tests were performed on Sample Serial Number AAAF188-80293

EUT Enclosure

The Navigator Transmitter enclosure is primarily constructed of plastic. It measures approximately 5.3 cm wide by 3.0 cm deep by 1.2 cm high.

Modification History

Mod. #	Test	Date	Modification
1	-	-	-

Modifications applied are assumed to be used on subsequent tests unless otherwise stated as a further modification.



EMC Test Data

Client:	Abbott Diabetes Care	Job Number:	J56294
Model:	Navigator Transmitter (SN AAAF188-80293)	T-Log Number:	T57080
Contact:	Chris Cherrison	Account Manager:	Susan Pelzl
Emissions Spec:	EN 300 220-3, FCC 15.231(e), EN	Class:	B
Immunity Spec:	EN 301 489-3	Environment:	Medical

Test Configuration #1

Local Support Equipment

Manufacturer	Model	Description	Serial Number	FCC ID
Abbott Diabetes Care	PRT03981	Sim-Vivo	-	-

Remote Support Equipment

Manufacturer	Model	Description	Serial Number	FCC ID
None				

Interface Cabling and Ports

Port	Connected To	Cable(s)		
		Description	Shielded or Unshielded	Length(m)
None				

EUT Operation During Emissions

The transmitter was configured normally to transmit data to the receiver once per minute. The Sim-Vivo was connected to the transmitter to simulate the data that would be obtained from a sensor that would normally be used. The sensor cannot be used since it only provides data when embedded in the skin of a user.

EUT Operation During Immunity

The transmitter was configured normally to transmit data to the receiver once per minute. The Sim-Vivo was connected to the transmitter to simulate the data that would be obtained from a sensor that would normally be used. The sensor cannot be used since it only provides data when embedded in the skin of a user. A spectrum analyzer was used to monitor transmissions in addition to the received data.

Performance Criteria

Normal operation:

Data from the receiver shall show one transmission per minute and no unintentional transmissions shall be recorded.

Stand-By Mode:

There shall be no transmissions from the transmitter.



EMC Test Data

Client:	Abbott Diabetes Care	Job Number:	J56294
Model:	Navigator Transmitter (SN AAAF188-80293)	T-Log Number:	T57080
		Account Manager:	Susan Pelzl
Contact:	Chris Cherrison		
Spec:	EN 300 220-3, FCC 15.231(e), EN 60601-1-2	Class:	B

Radiated Emissions

Test Specifics

Objective: The objective of this test session is to perform final qualification testing of the EUT with respect to the specification listed above.

Date of Test: 10/8/2004 and 10/11/04
 Test Engineer: David Bare
 Test Location: SVOATS #2

Config. Used: 1
 Config Change: None
 EUT Voltage: Battery

General Test Configuration

The EUT was located on the turntable for radiated emissions testing.

Unless otherwise specified, the measurement antenna was located 3 meters from the EUT.

Note, for testing above 1 GHz, the FCC specifies the limit as an average measurement. In addition, the FCC states that the peak reading of any emission above 1 GHz, can not exceed the average limit by more than 20 dB.

Ambient Conditions: Temperature: 25 °C
 Rel. Humidity: 71 %

Summary of Results

Run #	Test Performed	Limit	Result	Margin
1	RE, 30 - 4336MHz, Fundamental at 433.6 MHz	FCC 15.231(e)	Pass	67.9dBµV/m (2483.1µV/m) @ 433.564MHz (-5.0dB)
1	RE, 30 - 4336MHz, Maximized Emissions	FCC 15.231(e)	Pass	37.3dBµV/m (73.3µV/m) @ 867.128MHz (-15.6dB)
2	Radiated erp - fundamental and spurious signals	EN 300 220-3	Pass	Fundamental:-15dBm Spurious: -54 dBm
3	Bandwidth	FCC 15.231(c)	Pass	N/A

Modifications Made During Testing:

The following modifications were made to the EUT during testing in order to enable testing to requirements of the standard: The EUT transmits for 20 mS every 1 minute in normal operation. The test sample was modified to transmit once every 2 seconds. A 14 dB duty cycle correction was applied to the peak emission to calculate the average level.

Deviations From The Standard

No deviations were made from the requirements of the standard.



EMC Test Data

Client:	Abbott Diabetes Care	Job Number:	J56294
Model:	Navigator Transmitter (SN AAAF188-80293)	T-Log Number:	T57080
		Account Manager:	Susan Pelzl
Contact:	Chris Cherrison		
Spec:	EN 300 220-3, FCC 15.231(e), EN 60601-1-2	Class:	B

Run #1: Maximized emissions, EUT flat on table

Based on preliminary test data, the EUT flat on the table produced the highest amplitude emissions.

Frequency	Level	Pol	FCC 15.231(e)		Detector	Azimuth	Height	Comments
MHz	dB μ V/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
433.564	67.9	H	72.9	-5.0	Avg	280	1.0	
433.564	81.9	H	92.9	-11.0	Pk	280	1.0	

Based on preliminary test data, the EUT flat on the table produced the highest amplitude emissions.

Frequency	Level	Pol	FCC 15.231(e)		Detector	Azimuth	Height	Comments
MHz	dB μ V/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
867.128	37.3	H	52.9	-15.6	Pk	275	1.0	Peak reading, Average limit
867.128	37.3	H	52.9	-15.6	Pk	275	1.0	Peak reading, Average limit
1300.800	38.1	H	54.0	-15.9	Avg	100	1.0	Calculated from peak amplitude
3468.800	34.9	H	54.0	-19.1	Avg	0	1.0	Calculated from peak amplitude
3035.200	33.7	H	54.0	-20.3	Avg	0	1.0	Calculated from peak amplitude
2601.600	33.1	H	54.0	-20.9	Avg	100	1.0	Calculated from peak amplitude
1300.800	52.1	H	74.0	-21.9	Pk	100	1.0	
3468.800	48.9	H	74.0	-25.1	Pk	0	1.0	
3035.200	47.7	H	74.0	-26.3	Pk	0	1.0	
2601.600	47.1	H	74.0	-26.9	Pk	100	1.0	

Note 1: As the device transmitted only once every 2 seconds, great care was taken to ensure that the EUT azimuth and measurement antenna height were adjusted to obtain the maximum field strength from the device by moving the turntable and mast in small increments and waiting for a transmission from the device at each incremental angle.

Note 2: Measurements made using RBW = VBW = 120kHz below 1GHz, RBW=VBW=1MHz above 1GHz.

Run #2: Maximized emissions, EUT flat on table

Frequency	Level	Pol	EN 300 220-3		Detector	Azimuth	Height	Comments
MHz	dB μ V/m	v/h	Limit	Margin	Pk/QP/Avg	degrees	meters	
433.564	83.1	H	107.5	-24.4	Pk	285	1.8	substitute into dipole of -15 dBm
867.128	37.3	H	61.5	-24.2	Pk	275	1.8	substitute into dipole of -54 dBm

Output Power from substitutions with a dipole antenna from above data

Frequency (MHz)	Res BW	Output Power	Limit
433.564	100 kHz	-15 dBm	10 dBm
867.128	100 kHz	-54 dBm	-36 dBm



EMC Test Data

Client:	Abbott Diabetes Care	Job Number:	J56294
Model:	Navigator Transmitter (SN AAAF188-80293)	T-Log Number:	T57080
Contact:	Chris Cherrison	Account Manager:	Susan Pelzl
Spec:	EN 300 220-3, FCC 15.231(e), EN 60601-1-2	Class:	B

Run #3: Occupied Bandwidth (20 dB) performed on 10/11/04

Fo (MHz) 433.6

Limit (MHz) = 1.084

Measured BW = 253 kHz

IF BW used = 30 kHz

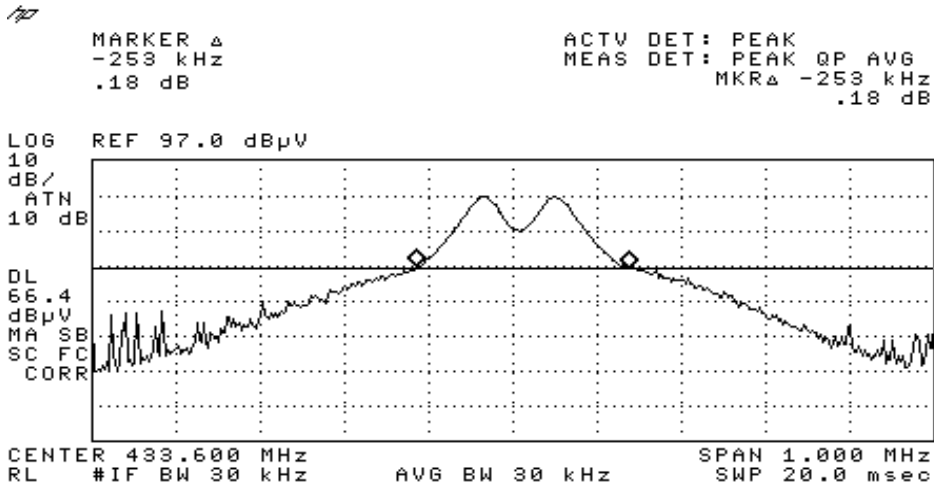


EXHIBIT 3: Photographs of Test Configurations

2 Pages

***EXHIBIT 4: Detailed Photographs of
Therasense (Abbott Diabetes Care) Model Navigator Continuous Glucose Monitor***

3 Pages

***EXHIBIT 5: Block Diagram of
Therasense (Abbott Diabetes Care) Model Navigator Continuous Glucose Monitor***

1 Page

***EXHIBIT 6: Schematic Diagrams of
Therasense (Abbott Diabetes Care) Model Navigator Continuous Glucose Monitor***

6 Pages

***EXHIBIT 7: Theory of Operation for
Therasense (Abbott Diabetes Care) Model Navigator Continuous Glucose Monitor***

3 Pages

EXHIBIT 8: Operator's Manual

20 Pages